

# **EPA REGISTRATION FILE 11603-54**

# PROCESSING REQUEST

Reg # 11603-54 Decision # S13S14

Description: New Product

## Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated 1-10-17

☐ Other:

## Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☒ New CSF(s) Dated 10-23-15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: G. Rowland

Division:

Phone:

Date:



## U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

11603-54

Date of Issuance:

1/10/17

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

FLUROXYPYR-MEPTYL  
TECHNICAL

## Name and Address of Registrant (include ZIP Code):

Ann Tillman  
Adama Agan Ltd.  
c/o Pyxis Regulatory Consulting  
4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, Wa 98832

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Date:

1/10/17

Kathryn Montague, Product Manager 23  
Herbicide Branch, Registration Division (7505P)

2. You are required to comply with the data requirements described in the DCI identified below:

a. Fluroxypyr 1-methylheptyl Ester: GDCI-128968-1498

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

3. The data requirements for storage stability (830.6320) are not satisfied. A one-year study is required to satisfy this data requirement. You have 18 months from the date of registration to provide these data.

4. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 11603-54."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/23/2015

If you have any questions, please contact Grant Rowland by phone at 703-347-0254, or via email at [rowland.grant@epa.gov](mailto:rowland.grant@epa.gov).

Enclosure



01/10/2017

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 11603-54

## Fluroxypyr-Meptyl Technical For Manufacturing Use Only

**ACTIVE INGREDIENT:**

Fluroxypyr 1-methylheptyl ester\* .....99.2%

**OTHER INGREDIENTS:**.....0.8%

**TOTAL**.....100.0%

\*CAS No. 81406-37-3

EPA Reg. No 11603-xx

EPA Est. No:

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

FIRST AID	
<b>If swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> </ul>
<b>If on skin:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in eyes:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-424-9300 for emergency medical treatment information.	
HOT LINE NUMBER	
You may also contact 1-800-308-5391 for emergency medical treatment information.	

Manufactured for:  
Adama Agan, Ltd.  
c/o Makhteshim Agan of North America, Inc.  
4515 Falls of Neuse Road, Suite 300  
Raleigh, NC 27609

Net Weight: XXXX lb.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION.** Harmful if swallowed or absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product in sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulating use only into herbicide end-use product for the following uses:

- **Terrestrial Nonfood Uses:** Non-crop land including rangeland, permanent pastures and conifer and tree plantations, airports, CRP acres, fence rows, and non-crop areas including communication transmission lines, electrical power and utility rights-of-way, fencerows, gravel pits, industrial sites, military lands, mining and drilling areas, non-irrigation ditchbanks, oil pads, parking lots, petroleum tank farms, pipelines, railroads, roadsides, storage areas, storm water retention areas, substations, unimproved rough turfgrasses, vacant lots and other non-crop residential areas; natural areas (open space) i.e., campgrounds, parks, prairie management, trails and trailheads, recreation areas, wildlife openings and wildlife habitat and management areas; roadsides; in and around farm buildings; Established turfgrass, including sod farms, residential lawns, golf courses, recreational, commercial and public turf areas including grazed areas on all of these listed sites
- This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning or equipment.

**Pesticide Storage:** Store in original container. Store in a cool, dry place.

**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Handling: Fiber drums with liners:** Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer drum and liner for recycling if available. If not available, dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If burned stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

**Nonrefillable Rigid Containers larger than 5 gal.:** Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.



Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

#### **LIMITATION OF WARRANTY AND LIABILITY**

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of ADAMA Agan, Ltd. However, it is impossible to eliminate all risks associated with the use of this product. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, ADAMA Agan, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of ADAMA Agan, Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, ADAMA Agan, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at ADAMA Agan, Ltd.'s election, the replacement of product.

[EPA approval date]

PYXIS REGULATORY CONSULTING, INC.

4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

January 26, 2016

MRID 498026-00

**ELECTRONIC DELIVERY**

Kathryn Montague (PM 23)  
Document Processing Desk (**REGFEE**)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

RE: ADAMA Agan, Ltd.  
Fluroxypyr-Meptyl Technical (EPA File Symbol 11603- )  
Application for New Pesticide Registration  
PRIA Category R334

Dear Ms. Montague,

On behalf of ADAMA Agan, Ltd., I am submitting an application for registration of Fluroxypyr-Meptyl Technical containing the active ingredient, fluroxypyr 1-methylheptyl ester. In support of this application, we submit the following documents:

1. Application for Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. The proposed label for Fluroxypyr-Meptyl Technical
4. Certification with Respect to Citation of Data (EPA Form 8570-34)
5. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
6. Public File Copy of the Data Matrix (EPA Form 8570-35)
7. Copy of PRIA payment
8. Letter of Authorization
9. Product Specific Data:

MRID	Guideline No.	Study Title
498026-01	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method for Fluroxypyr-Meptyl Technical. <b><i>Contains Confidential Business Information.</i></b>
498026-02	830.1700, 830.1800	Wasser, C. Purity Profile Study of 5 Batches of Fluroxypyr-meptyl Technical. <b><i>Contains Confidential Business Information.</i></b>
498026-03	830.6302, 830.6303, 830.6304, 830.6313, 830.6315, 830.6316, 830.6317, 830.6320, 830.7000, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840, 830.7950	White, G. A. Fluroxypyr-Meptyl Physical/Chemical Tests.

DOCUMENTUM



MRID	Guideline No.	Study Title
498026-04	830.6314, 830.7050, 830.7520	Tillman, A. M. Fluroxypyr-Meptyl Technical: Physical and Chemical Properties and Waiver Requests.
498026-05	OECD 420	Sanders, A. Fluroxypyr-meptyl TC: Acute Oral Toxicity in the Rat – Fixed Dose Method.
498026-06	OECD 402	Sanders, A. Fluroxypyr-meptyl TC: Acute Dermal Toxicity (Limit Test) in the Rat.
498026-07	OECD 403	Griffiths, D. R. Fluroxypyr-meptyl TC: Acute Inhalation Toxicity (Nose Only) Study in the Rat.
498026-08	OECD 405	Sanders, A. Fluroxypyr-meptyl TC: Acute Eye Irritation in the Rabbit.
498026-09	OECD 404	Sanders, A. Fluroxypyr-meptyl TC: Acute Dermal Irritation in the Rabbit.
498026-10	OECD 429	Sanders, A. Fluroxypyr-meptyl TC: Local Lymph Node Assay in the Mouse.

ADAMA Agan, Ltd. is using the selective method of data citation. As per EPA's interpretations of 40 CFR Parts 152.93(b)(2)(i), ADAMA Agan, Ltd. submitted notices of intent to apply and offer to pay to the extent required by FIFRA § 3(c)(1)(F). This action falls under PRIA category R334 (53: New MUP; unregistered source of active ingredient; selective data citation). The fee for this action is \$19,838 and has been paid.

We trust you will find this application complete. However, please feel free to contact me (253-853-7369; Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

## **Fluroxypyr Use Sites:**

### **From PastureGard HL (EPA Reg. No. 62719-637):**

Rangeland and permanent pastures, CRP acres, fence rows, and non-crop areas including non-irrigation ditchbanks, roadsides and around farm buildings using broadcast, foliar, basal bark or cut stump individual plant treatment methods.

### **From Vista Ultra (EPA Reg. No. 62719-586)**

CRP, rangeland and permanent grass pastures

Conifer and tree plantations

Airports, barrow ditches, communication transmission lines, electrical power and utility rights-of-way, fencerows, gravel pits, industrial sites, irrigation ditch banks, dry irrigation ditches or canals, military lands, mining and drilling areas, non-irrigation ditch banks, oil pads, parking lots, petroleum tank farms, pipelines, railroads, roadsides, storage areas, storm water retention areas, substations, unimproved rough turfgrasses, vacant lots and other non-crop residential areas

Natural areas (open space) i.e., campgrounds, parks, prairie management, trails and trailheads, recreation areas, wildlife openings and wildlife habitat and management areas

Established turfgrass, including sod farms, residential lawns, golf courses, recreational, commercial and public turf areas including grazed areas on all of these listed sites

### **From Surmount (EPA Reg. No. 62719-480)**

Rangeland and permanent grass pastures, CRP, non-cropland including fencerows, non-irrigation ditchbanks, roadsides and around farm buildings.

### **From Escalade Herbicide (EPA Reg. No. 228-442)**

Ornamental lawns (residential, industrial and institutional), parks cemeteries, athletic fields, golf courses (fairways, aprons, tees and roughs), sod farms.

Non-turf areas: Roadsides (including aprons and guardrails) and rights-of-way

### **From Alligare Fluroxypyr Herbicide (EPA Reg. No. 66330-385-81927)**

On-Farm non-cropland, CRP, rangeland and permanent pastures, non-crop land including industrial sites, non-irrigation ditchbanks, rights of way such as electrical power lines, communication lines, road sides and railroads including grazed areas within these sites, and pine plantations

## Rowland, Grant

---

**From:** Ann Tillman <Ann@PyxisRC.com>  
**Sent:** Tuesday, January 03, 2017 4:06 PM  
**To:** Rowland, Grant  
**Subject:** RE: EPA reg # 11603-LU  
**Attachments:** 011603-LU.20170103 Fluroxypyr Tech label.pdf; 011603-LU.20170103 Fluroxypyr Tech label\_chgs trkd.pdf; Fluroxypyr Use Sites.docx

Grant,

I made the label changes per your comments with the exception of removing/changing the use sites. We had done an assessment of use sites of approved end use product labels (see Word document, attached). The use sites on the Fluroxypyr-Meptyl Technical label are not listed on the Dow AgroScience's Starane F Technical label (EPA Reg. No. 62719-285). However, all of these use sites were approved on the labels of the following end-use products: EPA Reg. Nos. 62719-637, 62719-586, 62719-480, 228-442, and 66330-385-81927. ADAMA Agan wanted to ensure that its technical label was as comprehensive as possible, despite the apparent oversight for not listing these use sites on the Dow Starane F Technical label. Let me know if you have any further label changes or comments. Thanks.

Ann

**From:** Rowland, Grant [mailto:Rowland.Grant@epa.gov]  
**Sent:** January 03, 2017 3:20 PM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** EPA reg # 11603-LU

Hello Ann:

I am working on finishing up this new product for you but before I can stamp the label and approval letter, a few edits need to be made to the label. I have attached a pdf of the label with the comments that need to be addressed. If you could please return to me an updated label as soon as possible, I would greatly appreciate it. Thank you

-Grant

*Grant Rowland  
Herbicide Branch  
Registration Division  
Office of Pesticide Programs  
703-347-0254*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

16/AUG/2016

MEMORANDUM

Subject: Acute Toxicity Data Evaluation Record (DER) for Fluroxypyr Methyl  
Technical

Name of Pesticide Product: Fluroxypyr-Methyl Technical  
EPA File Symbol: 11603-LU  
DP Barcode: D432251  
Decision No.: 513514  
Action Code: R334  
PC Code: 128968 (Fluroxypyr 1-methylheptyl ester)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*  
Chemistry, Inerts and Toxicology Assessment Branch  
Registration Division (7505P)

Through: Masih Hashim, Ph.D., Team Leader Toxicology *M. Hashim*  
Chemistry, Inerts and Toxicology Assessment Branch  
Registration Division (7505P)

To: Kathryn Montague, Risk Manager Team 23  
Herbicide Branch  
Registration Division (7505P)

Applicant: Adama Agan Ltd.  
c/o Makhteshim Agan of North America, Inc.  
3120 Highwoods Blvd., suite 100  
Raleigh, NC 27604

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fluroxypyr 1-methylheptyl ester	99.2

<u>Other Ingredient(s):</u>	<u>0.8</u>
Total: 100.0%	



**ACTION REQUESTED:** The Risk Manager requests a review of acute toxicity studies submitted in support of Tide Fluroxypyr 1-methylheptyl ester Technical Fungicide, EPA File Symbol 11603-LU.

**BACKGROUND:** Adama Agan Ltd. has submitted six acute toxicity studies (MRIDs 498026-05 to 10) to support the registration of Fluroxypyr-Methyl Technical, EPA File Symbol 11603-LU. The submission also includes a label, company letter and basic CSF dated October 23, 2015 which must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

**GLP:** All studies were conducted in accordance with GLP.

**DEFICIENCIES:** None

**LABEL:** The following are the precautionary and first aid statements for this product, as obtained from the Label Review System:

**PRODUCT ID #:** 11603-54

**PRODUCT NAME:** Fluroxypyr-Meptyl Technical

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

## DATA EVALUATION RECORD

**Product Reg. No.:** 11603-LU

**Product Name:** Fluroxypyr-Methyl Technical

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 11603-LU:

<b>1. DP BARCODE:</b> 432251				
<b>2. PC CODE:</b> 128968				
<b>3. CURRENT DATE:</b> August 16, 2016				
<b>4. TEST MATERIAL:</b> Fluroxypyr-methyl TC: (Batch # JLFM79201; Purity: 98.2%; pH 5.9; white powder)				
<b>Study/Species/Lab Study # /Date</b>	<b>MRID</b>	<b>Results</b>	<b>Tox Cat</b>	<b>Core Grade</b>
Acute oral toxicity / rat Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0009 April 2, 2009, amended November 20, 2009 OCSPP 870.1100; OECD 420	49802605	LD <sub>50</sub> Females > 2000 mg/kg bw  The test item was prepared as a suspension in arachis oil BP. (Test material did not dissolve or suspend in distilled water.)  One female was tested at a limit dose of 2000 mg/kg in a sighting study. Four additional females were dosed at 2000 mg/kg.  All animals survived and gained weight. No clinical signs of toxicity were noted. No gross abnormalities were observed at necropsy.	III	A
Acute dermal toxicity / rat Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0010 April 21, 2009, amended November 20, 2009 OCSPP 870.1200; OECD 402	49802606	LD <sub>50</sub> > 2000 mg/kg bw (both sexes)  The test item was moistened with arachis oil BP prior to application.	III	A

		All rats survived. One female did not gain weight during the first week but all animals gained weight by study termination. No clinical signs of toxicity or dermal irritation were observed. No abnormalities were observed at necropsy.		
Acute inhalation toxicity / rat Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0014 May 5, 2009, amended November 4, 2009 OCSPP 870.1300; OECD 403	49802607	LC <sub>50</sub> > 6.11 mg/L (both sexes)  MMAD 3.69 GSD: 3.14  All animals survived. Two females lost weight during the study and one female did not gain weight. All other animals showed bodyweight gains. During exposure, increased respiratory rate and wet fur was noted for all animals. On removal from the chamber, all animals showed increased respiratory rate, wet fur, hunched posture and piloerection. The animals appeared normal by day 1. Red brown staining of the fur around the neck of one female was noted on day 1 only. At necropsy, abnormally dark lungs were noted in one female. No other abnormalities were observed.	IV	A
Primary eye irritation / rabbit Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0011 April 16, 2009, amended November 20, 2009 OCSPP 870.2400; OECD 405	49802608	3 males tested pH = 9.1 as a 10% aqueous preparation of the test material  A volume of 0.1 mL (approx. 94 mg) of test material was instilled into each eye.	IV	A



		No corneal opacity or iritis were observed. Positive conjunctival redness was observed in all eyes at one hour decreasing to a score of 1 at 24 hours. Scores of 1 were noted for chemosis and discharge at 1 and 24 hours. All eyes were free of irritation by 48 hours.										
Primary dermal irritation / rabbit Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0012 April 14, 2009, amended November 20, 2009 OCSPP 870.2500; OECD 404	49802609	3 males tested PDI = 0.0 (non-irritating)  pH 9.1 (as a 10% w/w aqueous preparation)  A quantity of 0.5 g of the test item was moistened sufficiently with 0.5 mL of distilled water to achieve a paste prior to application.  No dermal irritation was observed at any of the test sites.	IV	A								
Dermal sensitization /mouse Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0013 March 30, 2009, amended November 20, 2009 OCSPP 870.2600; OECD 429	49802610	This product is <u>not</u> a dermal sensitizer.  <table><thead><tr><th><u>% tested</u></th><th><u>Stimulation Index*</u></th></tr></thead><tbody><tr><td>5</td><td>1.19</td></tr><tr><td>10</td><td>0.94</td></tr><tr><td>25</td><td>1.28</td></tr></tbody></table> *Stimulation Index values < 3 are negative results.  Appropriate historical positive control study is provided.	<u>% tested</u>	<u>Stimulation Index*</u>	5	1.19	10	0.94	25	1.28	-	A
<u>% tested</u>	<u>Stimulation Index*</u>											
5	1.19											
10	0.94											
25	1.28											

**Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap  
W = Waived**





**FEE**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)**

**BARCODE No.:** D432250 **FILE SYMBOL No.:** 11603-LU **PRODUCT NAME:** Fluroxypyr-Meptyl Technical:  
**DECISION No.:** 513514 **PC Code(s):** 128968 **ACTION CODE:** R334 **FOOD Use:** Yes **COMPANY:** Adama  
Agan Ltd.

**This Document Contains Confidential Information**

**DATE OUT:** 08/30/2016

**SUBJECT:** Technical Product Chemistry Review  
Product Name: Fluroxypyr-Meptyl Technical

**FROM:** Indira Gairola / Product Chemistry Team  
CITAB/RD (7505P)

**TO:** Dominic Schuler / Kathryn Montague RM 23  
Herbicide Branch / RD (7505P)

**INTRODUCTION:**

Registrant is submitting registration application for subject product Fluroxypyr-Meptyl Technical produced by [REDACTED]. Applicant is submitting Basic CSF dated 10/23/15 and MRID #s 498026-01 to -04 for product chemistry Group A and Group B data to support this application. CITAB (Chemistry Team) has been asked to determine the acceptability of the aforementioned subject product chemistry data and Basic CSF 10/23/15.

**SUMMARY OF FINDINGS:**

1. Group A guidelines: 830.1550 (Product identity & composition) MRID 498026-01. Data for the identity and position of the product were provided. The active ingredient "Fluroxypyr-Meptyl Technical" is present at a nominal concentration of 99.2%. The product chemistry data submitted corresponding to Guideline 830.1550 satisfy the data requirements of 40CFR§158.320.

830.1600 (Description of materials used to produce the product) MRID #498026-01. The registrant provided a list of suppliers and MSDSs for the materials used to produce the product. The product chemistry data submitted corresponding to Guideline 830.1600 satisfy the data requirements of 40CFR§158.325.

830.1620 (Description of production process) 498026-01. The production process by was described by [REDACTED]. The product chemistry data submitted corresponding to Guideline 830.1620 satisfy the data requirements of 40CFR§ 158.330

**BARCODE No.:** D432250 **FILE SYMBOL No.:** 1603-LU **PRODUCT NAME:** Fluroxypyr-Meptyl Technical;  
**DECISION No.:** 513514 **PC Code(s):** 128968; **ACTION CODE:** R334; **FOOD Use:** Yes **COMPANY:** Adama  
Agan Ltd.

830.1670 (Discussion on the formation of impurities). 498026-01 A discussion of the origin and mechanism formation for the impurities in the product was provided. Applicant provided analyses of all process related impurities. The Analysis was performed using validated methods of technical by HPLC / UV. No impurities of toxicological concern were detected. External standard quantitation methods were used to quantify the levels of a.i. and associated impurities. As per CITAB based on the estimated impurities value the impurities are not of significant potential toxicological concern.

Data submitted corresponding to Guideline 830.1670 satisfy the data requirements of 40CFR§158.340.

830.1700 (Preliminary analysis) #498026-02. Results of a five-batch preliminary analysis were provided in. The total recovery content of a.i. ranged from 99.5-99.9%. These values are within the certified limits specified on the CSF dated 01/20/16 The product chemistry data submitted corresponding to Guideline 830.1700 satisfy the data requirements of 40CFR§158.345.

830.1750 (Certified limits) for Basic CSF dated 10/23/15. Certified limits were provided for the active ingredient Dicamba sodium, and upper certified limits were provided for the impurities in the product. Content of a.i. ranged from 96.2% -100% with an average of 99.2.82%. The proposed upper limit is 100 % and the lower limit is 96.2%. The product chemistry data submitted corresponding to Guideline 830.1750 satisfy the data requirements of 40CFR§158.350

830.1800 (Enforcement analytical method) MRID #498026-02. A description of the enforcement analytical method and its validation were provided. The Analysis of Dicamba sodium technical by HPLC equipped with UV detector using [REDACTED] The analysis of the five lots indicates an average ai concentration of 99.8 % purity. Average total closure of the five lots samples was reported. The product chemistry data submitted corresponding to Guideline 830.1800 satisfy the data requirements of 40CFR§158.355. For details please refer to the Confidential Appendix

2. Group B guidelines (physical-chemical properties) The Data submitted is listed in the following pages.

\*Quality control process information may be entitled to confidential treatment\*

**BARCODE No.:** D432250 **FILE SYMBOL No:** 1603-LU **PRODUCT NAME:** Fluroxypyr-Meptyl Technical;  
**DECISION No.:** 513514; **PC Code(s):** 128968; **ACTION CODE:** R334; **FOOD Use:** Yes **COMPANY:** Adama  
Agan Ltd.

#### **CONCLUSIONS:**

The (CITAB/ Product Chemistry Team has reviewed the product chemistry data submitted for “Fluroxypyr-Meptyl Technical” and concluded:

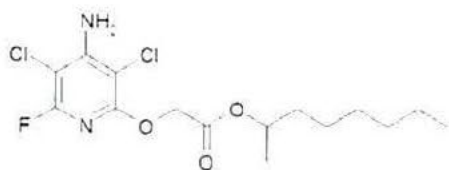
1. All product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The Basic dated CSF 10/23/15 is acceptable.
3. No impurity of significant toxicological concern was identified as per CITAB, for details please refer to the Confidential Appendix and summary of findings.
4. Product chemistry data corresponding to 830 series group B (physical-Chemical properties) are listed in the following pages.

**BARCODE No.:** D432250 **FILE SYMBOL No:** 1603-LU **PRODUCT NAME:** Fluroxypyr-Meptyl Technical:  
**DECISION No.:** 513514 **PC Code(s):** 128968; **ACTION CODE:** R334; **FOOD Use:** Yes **COMPANY:** Adama  
Agan Ltd.

## **IDENTITY**

Fluroxypyr-Meptyl Technical contains 99.2% fluroxypyr-meptyl. The Chemical Code is 128968 and the CAS No. is 81406-37-3. The CAS nomenclature is 1-methylheptyl [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate.

The molecular formula for fluroxypyr-meptyl is  $C_{15}H_{21}Cl_2FN_2O_3$  and it has a molecular weight of 367.2. The structure is shown below:



Fluroxypyr-Meptyl



**BARCODE No.:** D432250 **FILE SYMBOL No.:** 1603-LU: **PRODUCT NAME:** Fluroxypyr-Meptyl Technical:  
**DECISION No.:** 513514: **PC Code(s):** 128968; **ACTION CODE:** R334; **FOOD Use:** Yes **COMPANY:** Adama  
 Agan Ltd.

Table 2: Physical and Chemical Properties : Fluroxypyr-Meptyl Technical

GLN	Requirement	MRID	Status	Result or Deficiency												
830.6302	Color	498026-03	<u>A</u>	White												
830.6303	Physical state	498026-03	<u>A</u>	Fine powder												
830.6304	Odor	498026-03	<u>A</u>	Musty odor												
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	498026-03	<u>A</u>	The test substance did not show exothermic or endothermic reaction is therefore considered to be stable at room temperature												
830.6314	Oxidation/reduction; chemical incompatibility	498026-03	<u>A</u>	Does not contain oxidizing hazard agents												
830.6315	Flammability	498026-03	<u>W</u>	This solid product is a TGA1 and will not self-ignite nor is it highly flammable.												
830.6316	Explodability	498026-03	<u>W</u>	This solid product is a TGA1 and does not have the potential to explode; therefore it is requested that the requirement for this data be waived.												
830.6317	Storage stability		<u>I</u>	LLC agrees to conduct and submit it as a condition of product registration. Therefore it is requested that the Agency make this data a condition of registration												
830.6319	Miscibility		<u>NA</u>	Not an emulsifiable liquid to be diluted with petroleum solvent therefore it is not required.												
830.6320	Corrosion characteristics	498026-03	<u>A</u>	No visual evidence of corrosive action												
830.7000	pH	498026-03	<u>A</u>	5.9-6.10.												
830.7050	UV/Visible absorption	Cited 407403-03	<u>A</u>	<table><tr><td>UV-VIS absorption spectra</td><td>Neutral</td><td>Acidic</td><td>Alkaline</td></tr><tr><td>Wavelength of maximum (nm)</td><td>210.0</td><td>210.0</td><td>219.0</td></tr><tr><td>ε Value calculated</td><td>40673.4</td><td>41010.1</td><td>23804.7</td></tr></table>	UV-VIS absorption spectra	Neutral	Acidic	Alkaline	Wavelength of maximum (nm)	210.0	210.0	219.0	ε Value calculated	40673.4	41010.1	23804.7
UV-VIS absorption spectra	Neutral	Acidic	Alkaline													
Wavelength of maximum (nm)	210.0	210.0	219.0													
ε Value calculated	40673.4	41010.1	23804.7													
830.7100	Viscosity		<u>NA</u>	Solid												
830.7200	Melting point	498026-03	<u>A</u>	Technical sample melts 58.9°C												
830.7220	Boiling point		<u>NA</u>	Solid												
830.7300	Density	498026-03	<u>A</u>	1.261												
830.7550	Octanol / water Partition coefficient	498026-03	<u>A</u>	7.06 ( log =P <sub>ow</sub> ) @ pH 7.0												
830.7950	Vapor pressure	498026-03	<u>A</u>	Value for the vapor pressure of 4.4 x10 -4 Pa at 20°C is stated.												
	Water solubility		<u>NA</u>	.0.155mg/L												
	Dissociation Constant	498026-03	<u>A</u>	pKa=6.6												

**BARCODE No.:** D432250 **FILE SYMBOL No:** 1603-LU; **PRODUCT NAME:** Fluroxypyr-Meptyl Technical;  
**DECISION No.:** 513514; **PC Code(s):** 128968; **ACTION CODE:** R334; **FOOD Use:** Yes **COMPANY:** Adama  
Agan Ltd.

CONFIDENTIAL APPENDIX (is listed in the following pages)







Screen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D432250; **FILE SYMBOL No.:** 11603-LU (screen); **PRODUCT NAME:** Fluroxypyr-Meptyl Technical; **DECISION No.:** 513514; **PC Code(s):** 128968; **ACTION CODE:** R334; **FOOD Use:** Yes

**DATE OUT:** March 31, 2016

**SUBJECT:** 45/90 day screen results for technical product "Fluroxypyr-Meptyl Technical"

**FROM:** Shyam Mathur, Product Chemistry Team Leader, CITAB / RD (7505P)

SJB

**TO:** Dominic Schuler / Kathryn Montague, RM 23; Herbicide Branch / RD (7505P)

**Company Name:** ADAMA AGAN Ltd.

**Active Ingredient(s):** Fluroxypyr-1-methylheptyl ester (99.2%)

**MRID No(s):** 49802601 to 49802604

**CONCLUSION:**

**Deficiencies:** No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

**Group A:** All data submitted

**Group B:** All data submitted

**CSF:** Basic CSF (dated 10-23-2015) submitted (obtained from e-submission)

**Note to PM:** Please attach the proposed CSF (after Inert group of CITAB evaluation) and the draft label with the data package.

**DRAFT PRODUCT LABEL:** Not Submitted could not be found in e-submission

**Note to PM:** If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



25 March, 2015

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Adama Agan Ltd. (EPA Company Number 11603), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Dr. Tali Ehrlich  
Head of Global Regulatory Affairs  
ADAMA Agan Ltd.

cc: Pyxis Regulatory Consulting, Inc.

ADAMA  
Agan

DOCUMENTUM



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Adama Agan Ltd. c/o Pyxis Reg. Consulting, 4110 136th St. CT NW Gig Harbor WA (253)8537369	EPA Registration Number/File Symbol 11603-
Active Ingredient(s) and/or representative test compound(s) Fluroxypyr Technical	Date Jan. 26, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGA1	Product Name Fluroxypyr-Meptyl Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2016.01.25 06:05:01 -05'00'	Date Jan. 26, 2016	Typed or Printed Name and Title Ann M. Tillman, Agent
---------------	--	-----------------------	--



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>			EPA Reg. No./File Symbol <b>11603-</b>		Page <b>1</b> of <b>20</b>
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product Fluroxypyr-Meptyl Technical		
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	49802601	ADAMA Agan, Ltd.	OWN	
830.1600	Description of Materials Used to Produce the Product	49802601	ADAMA Agan, Ltd.	OWN	
830.1620	Description of Production Process	49802601	ADAMA Agan, Ltd.	OWN	
830.1650	Description of Formulation Process				Not Required <sup>1</sup>
830.1670	Discussion of Formation of Impurities	49802601	ADAMA Agan, Ltd.	OWN	
830.1700	Preliminary Analysis	49802602	ADAMA Agan, Ltd.	OWN	
830.1750	Certified Limits	49802601	ADAMA Agan, Ltd.	OWN	
830.1800	Enforcement Analytical Method	49802602 49802601	ADAMA Agan, Ltd. ADAMA Agan, Ltd.	OWN OWN	
830.6302	Color	49802603	ADAMA Agan, Ltd.	OWN	
830.6303	Physical State	49802603	ADAMA Agan, Ltd.	OWN	
830.6304	Odor	49802603	ADAMA Agan, Ltd.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	49802603	ADAMA Agan, Ltd.	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	49802604	ADAMA Agan, Ltd.	OWN	Waiver <sup>2</sup>
830.6315	Flammability	49802603	ADAMA Agan, Ltd.	OWN	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>			EPA Reg. No./File Symbol <b>11603-</b>		Page 2 of 20
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product  Fluroxypyr-Meptyl Technical		
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	49802603	ADAMA Agan, Ltd.	OWN	
830.6317	Storage Stability	49802603	ADAMA Agan, Ltd.	OWN	
830.6319	Miscibility				Not required <sup>3</sup>
830.6320	Corrosion Characteristics	49802603	ADAMA Agan, Ltd.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required <sup>4</sup>
830.7000	pH	49802603	ADAMA Agan, Ltd.	OWN	
830.7050	UV/Visible Absorption	47540703	Nufarm Limited	PAY	
830.7100	Viscosity				Not required <sup>5</sup>
830.7200	Melting Point/Melting Range	49802603	ADAMA Agan, Ltd.	OWN	
830.7220	Boiling Point/Boiling Range				Not required <sup>6</sup>
830.7300	Density/Relative Density/Bulk Density	49802603	ADAMA Agan, Ltd.	OWN	
830.7370	Dissociation Constants in Water	49802603	ADAMA Agan, Ltd.	OWN	
830.7520	Particle size, fiber length, diameter distribution	49802604	ADAMA Agan, Ltd.	OWN	Waiver <sup>7</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	49802603	ADAMA Agan, Ltd.	OWN	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------




## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date January 4, 2015		EPA Reg. No./File Symbol 11603-		Page 3 of 20	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product Fluroxypyr-Meptyl Technical			
Ingredient Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	49802603	ADAMA Agan, Ltd.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	49802603	ADAMA Agan, Ltd.	OWN	
870.1100	Acute Oral Toxicity: Rat	49802605	ADAMA Agan, Ltd.	OWN	
870.1200	Acute Dermal Toxicity: Rat	49802606	ADAMA Agan, Ltd.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	49802607	ADAMA Agan, Ltd.	OWN	
870.2400	Primary Eye Irritation: Rabbit	49802608	ADAMA Agan, Ltd.	OWN	
870.2500	Primary Dermal Irritation	49802609	ADAMA Agan, Ltd.	OWN	
870.2600	Dermal Sensitization	49802610	ADAMA Agan, Ltd.	OWN	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>4</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Generic Data Requirements</b>					
850.2100	Acute Avian Oral Toxicity	40244546 40244516		OLD OLD	See endnote/ Not required <sup>8</sup>
850.2200	Acute Avian Dietary Toxicity	40244517 42137301		OLD OLD	See endnote <sup>9</sup>
850.2400	Wild Mammal Toxicity				Not required
850.2300	Avian Reproductive Toxicity	42137303 42137304		OLD OLD	See endnote <sup>10</sup>
850.2500	Simulated or Actual Field Testing				Not required
850.1075	Freshwater Fish Toxicity	44080307 40244522		OLD OLD	See endnote <sup>11</sup>
850.1010	Freshwater Invertebrate Toxicity	40244520 40244521 40244524 42137308		OLD OLD OLD OLD	See endnote <sup>12</sup>

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date January 4, 2015			EPA Reg. No./File Symbol 11603-		Page 5 of 20
Applicant's / Registrant's Name & Address ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product Fluroxypyr-Meptyl Technical		
Ingredient Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	44080308 44080309 45725801 44080311 44080313 44080312	Dow AgroSciences, LLC	OLD OLD PAY OLD OLD OLD	See endnote <sup>13</sup>
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	44080314		OLD	See endnote <sup>14</sup>
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required
850.1400	Fish Early Life Stage (Freshwater)	48559401	Dow AgroSciences, LLC	PAY	See endnote <sup>15</sup>
850.1400	Fish Early Life Stage (Saltwater)				Not required
850.1500	Life Cycle Fish				Not required
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	44080348 44605403		OLD OLD	See endnote <sup>16</sup>
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required

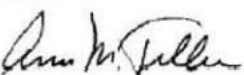
Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page 6 of 20	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Whole Sediment: Chronic Invertebrates Freshwater and Marine				Not required
850.3020	Honey Bee Acute Contact Toxicity	42137313		OLD	See endnote <sup>17</sup>
Special Study	Pollinator Chronic Toxicity – Honeybee Larvae			GAP	
Special Study	Pollinator Chronic Oral Toxicity – Honeybee Adult			GAP	
Special Study	Pollinator Acute Oral Toxicity – Honeybee Adult			GAP	
Special Study	Pollinator Acute Oral Toxicity – Honeybee Larvae			GAP	
850.3040	Semi-Field Test for Pollinators				Reserved
850.3030	Residue Analysis of Nectar and Pollen in Flowering Crops				Not required <sup>18</sup>
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required
870.6200	Acute Neurotoxicity – Rat				Waived <sup>19</sup>
870.3100	90-Day Oral: Rodent	44080316 42164502 42137337		OLD OLD OLD	See endnote <sup>20</sup>
870.3150	90-Day Oral: Non-Rodent	42137340		OLD	See endnote <sup>21</sup>
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 4, 2015



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date January 4, 2015			EPA Reg. No./File Symbol 11603-		Page 7 of 20
Applicant's / Registrant's Name & Address ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product Fluroxypyr-Meptyl Technical		
Ingredient Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3200	21/28-Day Dermal Toxicity	42137337		OLD	See endnote <sup>22</sup>
870.3250	90-Day Dermal Toxicity				See 870.3200
870.3465	90-Day Inhalation Toxicity				Waived <sup>23</sup>
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity				Waived <sup>24</sup>
870.4100	Chronic Oral Rodent	44080322		OLD	See endnote <sup>25</sup>
870.4200	Carcinogenicity	44080322 44080317		OLD OLD	See endnote <sup>26</sup>
870.3700	Reproduction/Developmental Toxicity Screening Test	44080319 40354013 44094901 40244509		OLD OLD OLD OLD	See endnote <sup>27</sup>
870.3800	2-Generation Reproduction: Rat	44080321		OLD	See endnote <sup>28</sup>
870.6300	Developmental Neurotoxicity Study				Not required
870.5100	Bacterial Reverse Mutation Test	44080323		OLD	See endnote <sup>29</sup>
870.5300, 830.5375	<i>In vitro</i> Mammalian Cell Assay	44080325		OLD	See endnote <sup>30</sup>

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date <b>January 4, 2015</b>			EPA Reg. No./File Symbol <b>11603-</b>		Page <b>8</b> of <b>20</b>
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product  Fluroxypyr-Meptyl Technical		
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5385, 870.5395, 870.5450; 870.5550	<i>In vivo</i> Cytogenetics and Other Effects	44080326		OLD	See endnote <sup>31</sup>
870.7485	Metabolism and Pharmacokinetics	44080327			
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration				Not required
870.7800	Immunotoxicity	48581311	Dow AgroSciences LLC	PAY	See endnote <sup>32</sup>
875.1100	Dermal Exposure – Outdoor		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>33</sup>
875.1200	Dermal Exposure - Indoor				Not required
875.1300	Inhalation Exposure – Outdoor		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>33</sup>
875.1400	Inhalation Exposure - Indoor				Not required
875.1500	Biological Monitoring		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>33</sup>
875.1600	Data Reporting and Calculations		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>33</sup>
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 4, 2015

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date January 4, 2015			EPA Reg. No./File Symbol 11603-		Page 9 of 20
Applicant's / Registrant's Name & Address ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product Fluroxypyr-Meptyl Technical		
Ingredient Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1700	Product Use Information		Agricultural Handlers Exposure Task Force	OWN	See endnote <sup>33</sup>
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues				Not required <sup>34</sup>
875.2200	Soil Residue Dissipation		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
875.2400	Dermal Exposure		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
875.2500	Inhalation Exposure		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>


Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date <b>January 4, 2015</b>			EPA Reg. No./File Symbol <b>11603-</b>		Page <b>10</b> of <b>20</b>
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product  Fluroxypyr-Meptyl Technical		
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2600	Biological Monitoring		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
875.2700	Product Use Information		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
875.2800	Descriptions of Human Activity		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
875.2900	Data Reporting and Calculations		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
875.3000	Nondietary Ingestion Exposure		Outdoor Residential Exposure Task Force Agricultural Re-Entry Task Force	OWN OWN	See endnote <sup>35</sup>
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 4, 2015



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>11</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet Size Spectrum		Spray Drift Task Force	OWN	See endnote <sup>36</sup>
202-1	Droplet Size Spectrum		Spray Drift Task Force	OWN	See endnote <sup>36</sup>
850.4100	Tier 1: Seedling Emergence	44094902		OLD GAP	See endnote <sup>37</sup>
850.4150	Tier 1: Vegetative Vigor	44094902		OLD GAP	See endnote <sup>38</sup>

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>12</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.5400	Tier 1: Aquatic Plant Growth	45011602 44080338 44744001 45011603 44080340 42137312 44080337 45011601 45011605 40244526 45011607 44080341 45011606 45011609		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD GAP	See endnote <sup>39</sup>
850.4100	Tier 2: Seedling Emergence			GAP	See endnote <sup>40</sup>
850.4150	Tier 2: Vegetative Vigor			GAP	See endnote <sup>41</sup>

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>13</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.5400	Tier 2: Aquatic Plant Growth	45011602 44080338 44744001 45011603 44080340 42137312 44080337 45011601 45011605 40244526 45011607 44080341 45011606 45011609		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD GAP	See endnote <sup>42</sup>
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required


Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**


Date <b>January 4, 2015</b>			EPA Reg. No./File Symbol <b>11603-</b>	Page <b>14</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel			Product  Fluroxypyr-Meptyl Technical		
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4550	Cyanobacteria Toxicity	44080336 45011604 45011608		OLD OLD OLD	See endnote <sup>43</sup>
Special Study	Compost study			GAP	See endnote <sup>44</sup>
835.2120	Hydrolysis	40244539		OLD	See endnote <sup>45</sup>
835.2240	Photodegradation in Water	44080342		OLD	See endnote <sup>46</sup>
835.2410	Photodegradation in Soil	44080343		OLD	See endnote <sup>47</sup>
835.2370	Photodegradation in Air				Not required
835.4100	Aerobic Soil Metabolism	42137317		OLD	See endnote <sup>48</sup>
835.4200	Anaerobic Soil Metabolism				Not required <sup>49</sup>
835.4300	Aerobic Aquatic Metabolism	44080345		OLD	See endnote <sup>50</sup>
835.4400	Anaerobic Aquatic Metabolism	44080344		OLD	See endnote <sup>51</sup>
835.1230	Leaching/Adsorption/Desorption	42137319		OLD	See endnote <sup>52</sup>
835.1410	Volatility – Laboratory				Not required <sup>53</sup>
835.8100	Volatility – Field				Not required
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 4, 2015

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>15</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100	Soil Field Dissipation Study	44080347 44896702 45204201 45204202		OLD OLD OLD OLD	See endnote <sup>54</sup>
835.6200	Aquatic Sediment Field Dissipation Study				Not required <sup>55</sup>
835.6300	Forest Field Dissipation Study				Not required
835.6400	Combination and Tank Mixes				Not required
835.7100	Ground Water Monitoring				Not required
850.6100	Environmental Chemistry Methods	44080346 44896703 45084601		OLD OLD OLD GAP	See endnote <sup>56</sup>
860.1300	Nature of the Residue: Plants	40244528 42137344		OLD OLD	
860.1300	Nature of the Residue: Livestock	44080351 42137345 42137346 40244529		OLD OLD OLD OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 4, 2015

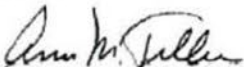
## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>16</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product  Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1850	Confined Rotational Crops	42137320 44080350		OLD OLD	
860.1340	Residue Analytical Methods	42164505 42164506 40244531 42137350 44080354 40244530 45157403		OLD OLD OLD OLD OLD OLD OLD	
860.1360	Multiresidue Method	42137347		OLD	
860.1380	Storage Stability	44080355		OLD	
860.1500	Magnitude of the Residue in Plants: grass	45157405		OLD	
860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	40244538 42137348		OLD OLD	
860.1400	Nature and Magnitude of the Residue in Potable Water				Not required
860.1400	Magnitude of the Residue in Fish				Not required
860.1400	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 4, 2015



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date <b>January 4, 2015</b>		EPA Reg. No./File Symbol <b>11603-</b>		Page <b>17</b> of <b>20</b>	
Applicant's / Registrant's Name & Address  ADAMA Agan Ltd. P.O. Box 262 Ashdod, Israel		Product Fluroxypyr-Meptyl Technical			
Ingredient <b>Fluroxypyr 1-methylheptyl ester (Chemical Code 128968)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1460	Magnitude of the Residue in Food Handling Establishments				Not required
860.1900	Field Rotational Crops				Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2015
--	--	----------------------

## Endnotes for Data Matrix for Fluroxypyr-Meptyl Technical

- 
- <sup>1</sup> **830.1650 - Description of Formulation Process:** These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- <sup>2</sup> **830.6314 – Oxidation/Reduction:** The molecular structure of Fluroxypyr-Meptyl Technical does not contain any oxidizing groups (such as peroxides, chlorates, perchlorates, nitrates, bromates, chromates, etc.) and does not contain any other component that would be an oxidizing or reducing agent. The EEC A17 Cone Test was carried out with 2 parts Fluroxypyr-Meptyl Technical to one part cellulose (MRID 49802603). In this test, Fluroxypyr-Meptyl Technical failed to give a vigorous reaction (burning was superficial only) and the conclusion was that fluroxypyr-meptyl is not a serious oxidation hazard. ADAMA requests a waiver from the requirement for evaluation of the reducing action of Fluroxypyr-Meptyl Technical based on the fact that Fluroxypyr-Meptyl Technical does not contain any other component that would be a reducing agent. Fire extinguishing methods (dry chemical, foam or carbon dioxide extinguishing methods) have been identified (MRID 49802604).
- <sup>3</sup> **830.6319 – Miscibility:** This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Fluroxypyr-Meptyl Technical is a solid and not an emulsifiable liquid to be diluted with petroleum solvents. This data requirement is not applicable to Fluroxypyr-Meptyl Technical.
- <sup>4</sup> **830.6321 – Dielectric Breakdown Voltage:** These data are not required unless the product is an end-use product. This data requirement is not applicable to Fluroxypyr-Meptyl Technical.
- <sup>5</sup> **830.7100 – Viscosity:** These data are not required unless the product is a liquid. This data requirement is not applicable to Fluroxypyr-Meptyl Technical because it is a solid.
- <sup>6</sup> **830.7220 – Boiling Point/Boiling Range:** This data requirement is not applicable to Fluroxypyr-Meptyl Technical because it is a solid.
- <sup>7</sup> **830.7520 – Particle size, fiber length, diameter distribution:** ADAMA is seeking a waiver for this data requirement for Fluroxypyr-Meptyl Technical because the technical grade is not a water-insoluble material and is not a fibrous material.
- <sup>8</sup> **850.2100 –** The studies cited were considered acceptable and satisfy the data requirement as per the Sept. 8, 2014 Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments to be Conducted in Support of the Registration Review for Fluroxypyr-MHE (Problem Formulation). The Problem Formulation also stated that acute avian passerine data were not required.
- <sup>9</sup> **850.2200 –** The studies cited were considered acceptable and satisfy the data requirement as per the Problem Formulation.
- <sup>10</sup> **850.2300 –** The studies cited were considered acceptable and satisfy the data requirement as per the Problem Formulation.
- <sup>11</sup> **850.1075 –** The studies cited were considered acceptable and satisfy the data requirement as per the Problem Formulation.
- <sup>12</sup> **850.1010 –** The studies cited were considered acceptable and satisfy the data requirement as per the Problem Formulation. Note: Although MRID 40244521 appears to correspond to a chronic study, it was listed as an acute study for fluroxypyr acid and is cited here.
- <sup>13</sup> **850.1025, 850.1035, 850.1045, 850.1055, 850.1075 –** The studies cited were considered acceptable and satisfy the data requirement as per the Problem Formulation.
- <sup>14</sup> **850.1300 –** The study cited was considered acceptable and satisfy the data requirement as per the Problem Formulation.
- <sup>15</sup> **850.1400 –** The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>16</sup> **850.1710, 850.1730, 850.1850 –** The studies cited was considered acceptable and satisfy the data requirement as per the Problem Formulation.



## Endnotes for Data Matrix for Fluroxypyr-Meptyl Technical

---

- <sup>17</sup> **850.3020** – The study cited satisfies the data requirement as per the Problem Formulation.
- <sup>18</sup> **850.3030** – Not required as per Feb. 19, 2015 EPA memorandum (DP Barcode D424686).
- <sup>19</sup> **870.6200** – This data requirement was waived as per the May 29, 2014 Fluroxypyr Methylheptyl Ester, Human Health Assessment Scoping Document in Support of Registration Review (DP Barcode D418559) (Scoping Document).
- <sup>20</sup> **870.3100** – The studies cited were considered acceptable and satisfy the data requirement as per the Scoping Document.
- <sup>21</sup> **870.3150** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>22</sup> **870.3200** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>23</sup> **870.3465** – This data requirement was waived as per the Scoping Document.
- <sup>24</sup> **870.6200** – This data requirement was waived as per the Scoping Document.
- <sup>25</sup> **870.4100** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>26</sup> **870.4200** – The studies cited were considered acceptable and satisfy the data requirement as per the Scoping Document.
- <sup>27</sup> **870.3700** – The studies cited were considered acceptable and satisfy the data requirement as per the Scoping Document.
- <sup>28</sup> **870.3800** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>29</sup> **870.5100** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>30</sup> **870.5300, 870.5375** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>31</sup> **870.5385, 870.5395, 870.5450, 870.5550** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>32</sup> **870.7800** – The study cited was considered acceptable and satisfies the data requirement as per the Scoping Document.
- <sup>33</sup> **875.1100, 875.1300, 875.1500, 875.1600, 875.1700** – ADAMA Agan, Ltd. is a member in good standing with the Agricultural Handler Exposure Task Force.
- <sup>34</sup> **875.2100** – These data were not required as per the Scoping Document.
- <sup>35</sup> **875.2200, 875.2400, 875.2500, 875.2600, 875.2700, 875.2800, 875.2900, 875.3000** – ADAMA Agan, Ltd. is a member in good standing with the Agricultural Re-Entry Task Force and Outdoor Residential Exposure Task Force.
- <sup>36</sup> **201-1, 202-1** – ADAMA Agan, Ltd. is a member in good standing with the Spray Drift Task Force.
- <sup>37</sup> **850.4100** – MRID 44094902 was classified as supplemental for Tier I and partially satisfies the requirement as per the Problem Formulation. This data requirement was also considered a data gap and EPA is requiring data through the Registration Review program. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.
- <sup>38</sup> **850.4150** – MRID 44094902 was classified as supplemental for Tier I and partially satisfies the requirement as per the Problem Formulation. This data requirement was also considered a data gap and EPA is requiring data through the Registration Review program. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.



## Endnotes for Data Matrix for Fluroxypyr-Meptyl Technical

---

- <sup>39</sup> **850.4400, 850.5400** – The studies cited satisfy the data requirement, except toxicity with the freshwater diatom, as per the Problem Formulation. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.
- <sup>40</sup> **850.4100** – This data requirement was considered a data gap and EPA is requiring data through the Registration Review program. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.
- <sup>41</sup> **850.4150** – This data requirement was considered a data gap and EPA is requiring data through the Registration Review program. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.
- <sup>42</sup> **850.4400, 850.5400** – The studies cited satisfy the data requirement, except toxicity with the freshwater diatom, as per the Problem Formulation. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.
- <sup>43</sup> **850.4550** – The studies cited were considered acceptable and satisfy the data requirement as per the Problem Formulation.
- <sup>44</sup> **Compost Study** – This data requirement was identified as a data gap in the Problem Formulation. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.
- <sup>45</sup> **835.2120** – The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>46</sup> **835.2240** – The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>47</sup> **835.2410** – The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>48</sup> **835.4100** – The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>49</sup> **835.4200** – These data are not required as per the Problem Formulation.
- <sup>50</sup> **835.4300** – The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>51</sup> **835.4400** – Although the study cited was classified as supplemental, no additional data were required and this study satisfies the data requirement as per the Problem Formulation.
- <sup>52</sup> **835.1230** – The study cited was considered acceptable and satisfies the data requirement as per the Problem Formulation.
- <sup>53</sup> **835.1410** – These data are not required as per the Problem Formulation.
- <sup>54</sup> **835.6100** – The studies cited satisfy the data requirement as per the Problem Formulation.
- <sup>55</sup> **835.6200** – Fluroxypyr-Meptyl Technical is not proposed for aquatic uses. Therefore, these data are not required.
- <sup>56</sup> **850.6100** – This data requirement was identified as a data gap in the Problem Formulation. When the DCI is issued, ADAMA Agan, Ltd. will address the data requirements identified in the DCI.

**Ann Tillman**

---

**From:** notification@pay.gov  
**Sent:** January 25, 2016 6:13 AM  
**To:** Ann Tillman  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25PINS7L  
Agency Tracking ID: 74946788971  
Transaction Type: Sale  
Transaction Date: 01/25/2016 06:12:46 AM EST

Account Holder Name: Jeff Welsh

Transaction Amount: \$19,838.00  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*3006

Registration Number:  
Company Name: Adama Agan Ltd.  
Company Number: 11603  
Action Code: R334

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number Adama Agan Ltd./11603-	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Adama Agan Ltd./Fluroxypyr-Meptyl Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Adama Agan Ltd. c/o Pyxis Regulatory Consulting 4110 136th St. Ct. NW Gig Harbor, WA 98832  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 62719-285  Product Name Starane F Technical	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R334 (53: New MUP with unregistered source of active ingredient). The fee which has been paid is \$19,838.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55.12, 110.24, 551.2 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date Jan. 26, 2016	



\*Confidential Statement of Formula may be entitled to confidential treatment\*